Best Practice in the Ethics and Governance of Service Evaluation

Guidelines for evaluators and commissioners of evaluation in health and social care

Introduction

Mechanisms and structures for governance and ethical review of research (including evaluative research) are well established¹. For service evaluation this remains at best locally driven, variable or absent.

These guidelines aim to address this situation. They are aimed at anyone conducting service evaluations within health and social care in the West of England.

The guidelines were developed in the West of England following a piece of work using Delphi consensus technique with stakeholders based in universities, health organisations, and patient and public contributors to develop a framework for the governance of service evaluation and a code of good practice around ethics.

The guidance provides links to available resources and includes practical examples of forms and checklists to assist with governance and ethical review.

Definition and uses of service evaluation

'A study in which the systematic collection and analysis of data is used to judge the quality or worth of a service or intervention, providing evidence that can be used to improve it.' (West of England Evaluation Strategy Group, 2013)²

Service evaluation is used for new and existing services across the spectrum of effectiveness, safety and experience. It is used for innovation to support the evidence base for commissioning or service development. Evaluation is crucial to ensuring that our local population get the best care. Organisations should

 $^{^1}$ The NHS Heath Research Authority (HRA) is one of a number of bodies with responsibilities for the regulation and governance of research in the UK.

² The West of England Evaluation Strategy Group was hosted by the former NIHR CLAHRC West to create a culture of evaluation in health and care across the region and support the spread of best practice. Its members included NHS organisations, the West or England Academic Health Science Network, Bristol Health Partners, the Avon Primary Care Research Collaborative, local universities and two public contributors. It was disbanded in 2018.

consider whether they can afford not to evaluate. Without evaluation, how will they know they are meeting the aims they set out to achieve?

It is good practice for an organisation to provide support for service evaluation. This includes having a strategy, nominated lead and register of all service evaluations in place.

The following principles should guide best practice in the governance of service evaluation:

1. Leadership, roles and responsibilities

There should be a nominated lead within each organisation with authority to provide the governance of service evaluation. Their role includes:

- Holding a register of projects to avoid duplication and to check compliance with organisation policies and procedures, including information governance and data protection. The register is a valuable source of information to the whole organisation. Download a <u>Sample Register</u>
- Throughout the duration of the project, ensuring internal peer review for ethical issues (and risks), methodological rigour, and acceptability to stakeholders such as staff, patients/service users and their families.
- Quality assuring the planned approach to ensure that it is proportionate, feasible, and has a clear purpose which is linked to the organisation's priorities and has an identified lead responsible for its delivery. Also, to ensure that it has utility and that plans are in place to share, use and feedback to those who took part. Download a sample <u>Quality Assurance Checklist</u>
- Checking contractual and insurance responsibilities are adequate.
- Making judgements whether the evaluator is suitable to conduct the evaluation with the population under study. For example, taking account of issues such as independence, political interest. Also, whether they have one of the following: a professional registration, have had Disclosure and Barring Service (DBS) checks, hold a research passport or have suitable references.
- Convening a wider reference group (including patient/service user or public representation) to discuss and approve complex evaluations.

2. Design and Review

The NHS Heath Research Authority (HRA) provides a <u>decision tool</u> that can be completed to determine if the project is a service evaluation. A record of the

outcome must be kept for audit purposes. The HRA also provide a helpful decision-making table

Service evaluation needs to consider the diverse nature of society and ensure that the right stakeholders, including patients and the public, are involved in the design, delivery and reporting of the evaluation.

3. Ethical Review

Any study, whether research, evaluation, quality improvement or audit should adhere to the following ethical guidelines.

Organisations, or those involved in a service evaluation, must ensure that they monitor and address ethical issues throughout the evaluation process.

All service evaluations should be reviewed to identify and address ethical issues and risks, and develop a 'risks and issues register'. This review does not need to be conducted by an external body, such as the Research Ethics Service (RES); however we recommend this involves a peer review by an individual or committee against an agreed checklist assessing risk, ethical issues and governance arrangements. For sample checklists, see the <u>Quality Assurance</u> <u>Checklist</u>, <u>Evaluation Risk Register</u> and resources included in the NHS Evaluation Works toolkit, such as the <u>Evaluation Planning Checklist</u>

Where service evaluations involve a degree of participation (ie involvement in an advisory group), ethical review should take account of matters relating to partnership, collaboration and power, community rights, ownership and dissemination of data. The UK Evaluation Society (UKES) has supported the development of a <u>set of guidelines</u> for patient and public involvement in evaluation.

4. Safeguards

All service evaluations should ensure that they have adequate safeguards in place to protect the participant, service and organisation from harm.

Where service evaluations involve human participants, this should include seeking appropriate informed consent taking into account risk, vulnerability and capacity of the participant. For example:

- Consent should be appropriate to the participant's age, learning ability, language, religious and cultural beliefs
- Consent should be explicit verbal or written consent where participants are identifiable or where their identifiable data is involved (or qualitative methods are being used)

- Consent may also be implied through the completion of activities such as surveys
- Consent may not be needed if the data is accessed in an anonymised form. However, to comply with data protection regulations (GDPR), participants need to opt out if they do not want their anonymised data used for other evaluation or service improvement purposes. For information on consent to share anonymised patient data see <u>your NHS</u> <u>data matters</u>
- All information provided about the evaluation should be accessible to enable fair and equitable access to the study. It should take account of the potential sensitivities, emotional impact and distress that may arise from the service evaluation.
- All information should make sure that it is clear that participation is voluntary and they can withdraw at any time without adverse consequences.

Examples of consent forms and participant information sheets can be viewed <u>here</u>

Service evaluations need to conduct a risk benefit analysis using their quality assurance and ethical review checklists to ensure that the benefits of conducting an evaluation outweigh the risks; ensure that risks and issues are mitigated and managed and benefits maximised.

5. Evaluator Conduct

Evaluators should adhere to a code of conduct in accordance with their own discipline or to specific guidelines such as:

- UKES <u>Guidelines for Good Practice in Evaluation</u> good practice and capabilities guidance
- UKES <u>Framework of Evaluation Capabilities</u>
- <u>Market Research Society (MRS) Code</u>

The evaluator should ensure they have the skills, experience and support to undertake the evaluation. This might require coaching, training or supervision. NIHR ARC West is the local provider of evaluation training for people working in its <u>partner organisations</u> in the West of England and also provides links to <u>other training opportunities</u>. The UK Evaluation Society (UKES) <u>South West of England and South Wales Regional Network</u> offers peer support to those in the region working on evaluation or with evaluation evidence.

Evaluators should declare conflicts of interest. For instance, a service manager conducting an evaluation may have a conflict of interest. While this doesn't prevent them from conducting the evaluation, they will need to declare the

conflict of interest on an appropriate form for this purpose. Example 'declaration of interest' forms can be viewed at:

- National Institute for Health and Care Excellence (NICE)
- NHS England

Evaluators should be mindful of and respond to ethical issues throughout the whole period of evaluation.

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